## REMARKS

Applicant respectfully requests reconsideration. Applicant has amended the specification to include priority application information. Claims 1-12 are pending in this application. Claims 1 and 2 are amended herein. Support for this amendment can be found, for example, on pages 3 and 5 of the application as filed. No claims have been cancelled or added. As a result, claims 1-12 are still pending for examination, claim 1 being an independent claim. No new matter has been added.

### Priority

The Office Action indicates that Applicant has not properly claimed the benefit of the prior-filed provisional application (US 60/504,516) filed on September 18, 2003. Applicant submits herewith a petition to correct unintentionally delayed benefit claim under 37 C.F.R. §1.78(a)(6) along with the surcharge set forth in § 1.17(t), and a statement that the entire delay was unintentional. A reference to the prior-filed provisional application has been included in the Supplemental Application Data Sheet submitted herewith. Applicant has also amended the specification to include the priority application information. Applicant respectfully requests entry of this amendment. No new matter has been added.

### Rejections Under 35 U.S.C. §103

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mimura et al. (Alimentary Pharmacology and Therapeutics, 2002).

The Office Action alleges that "Mimura, et al. teach that antibiotics, such as metronidazole, are effective for the treatment of pouchitis" and that "Tracy and Webster teach that metronidazole is well tolerated at the doses of the instant invention, and one of skill in the art would not be dissuaded from using such doses precisely because they are indicated for some infections." (pages 4-5 of the Office Action).

Without conceding the correctness of the rejection and solely in the interest of expediting prosecution, Applicant has amended claim 1 to recite "the effective amount is administered in a

single dosage." Support for this amendment can be found, for example, on pages 3 and 5 of the application as filed. As discussed below, neither Mimura et al. nor Tracy and Webster teach or suggest the local administration of 2,000 mg to 10,000 mg of metronidazole in a single dosage for treating patients with mucositis.

"[T]he focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge" (MPEP § 2141). At the time of filing the instant application, it was known in the art that high conventional dosing of anti-fungal azole compounds was associated with undesired side effects. The distal components of non-fungal and/or non microbial induced mucositis were not treatable by conventional dosing because of low local concentrations of therapeutics. Based on the teachings of the cited art, one of ordinary skill in the art would not have reasonably expected to be able to treat patients with mucositis of the distal intestinal tract because high dosing was known to result in undesired side-effects, while conventional dosing resulted in low and ineffective concentrations of the drugs at the distal intestinal tract.

The instant application is based on the surprising discovery that high doses of anti-fungal azole compounds can be used for treating mucositis of the distal intestinal tract if administered locally in an effective amount. Applicant respectfully submits that neither Mimura et al. nor Tracy and Webster teach or suggest local administration of 2,000 mg to 10,000 mg of metronidazole in a single dosage for treating patients with pouchitis. Mimura et al. teach oral administration of 400-500 mg metronidazole twice a day. Tracy and Webster teach that the drug is "completely and promptly absorbed after oral intake" and that after an oral dose "over 75% of labeled metronidazole is eliminated in the urine, largely as metabolites; only about 10% is recovered as unchanged drug" (page 1106, second column). Based on these teachings, one of skill would not expect a high and effective concentration of metronidazole to be locally "administered" to the distal intestinal tract as the drug would be completely and promptly absorbed after oral intake. Moreover, since high conventional dosing of anti-fungal azole compounds was associated with undesired side effects, one of ordinary skill in the art would not have been motivated or have a reason to use a higher dosage of the anti-fungal azole compound for direct application to the distal intestinal tract for treating

pouchitis. The Office Action has failed to establish any factual support for the assertion that direct application of the claimed dosage of azole compounds to the distal intestinal tract would be tolerated and/or effective for treating pouchitis.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

## CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C0875.70019US02.

Dated: September 29, 2010

Respectfully submitted,

By _____

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